

REMARKS

Initially, the Examiner has rejected claims 52 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as his invention. However, it is not apparent to Applicant where Applicant fails to particularly point out and distinctly claim the subject matter of the invention for this claim. Thus, Applicant has not amended this claim and respectfully requests the Examiner to be more specific with regard to this rejection.

Nevertheless, Applicant has found that there are two claims numbered "53" in the listing of the claims. Therefore, Applicant has cancelled the second claim numbered "53" and resubmitted it as new claim 55. Thus, claims 40-57 are the pending claims.

With respect to the rejection of the claims based upon the prior art, the Examiner has rejected the claims 40-54 under 35 U.S.C. 103(a) as being obvious and, therefore, unpatentable over Kirschner et al. U.S. Patent No. 6,899,890 ("Kirschner") in combination with Herschler U.S. Patent No. 4,997,823 ("Herschler") and Kelly International Patent Publication No. WO 02/092097 ("Kelly"). The Applicant understands that the Examiner essentially alleges that the present invention is obvious because, while the prior art does not teach the vaginal delivery of azithromycin in combination with a prostaglandin for the treatment of infection or surgical trauma, both of these types of drugs are alleged to be known to be delivered vaginally, and therefore, the Examiner believes it would have been obvious to one of ordinary skill in the art that these drugs could be delivered vaginally in combination. In response to Applicant's argument that co-administration of an antibiotic and prostaglandin provides a synergistic effect not found in the administration of each ingredient by itself, the Examiner firstly asserts that the amounts of the active ingredients are not known and secondly asserts that the data in the present specification only relates to a combination of azithromycin and misoprostol, and it not commensurate with the full scope of the claimed invention.

In response, Applicant respectfully traverses this rejection. First, Applicant has amended claims 40 and 44 to indicate that the prostaglandin includes misoprostol. Misoprostol is a species of prostaglandin that has been shown in the application to produce a synergistic effect in the treatment of pelvic infections and in reducing surgical traumas.

Thus, while Applicant finds it hard to believe the Examiner could have asserted that it would have been obvious to vaginally administer an azithromycin and a prostaglandin based upon the prior art cited, Applicant believes the limitation of the prostaglandin to misoprostol even further narrows the claims to such an extent that one of ordinary skill in the art would clearly have not been motivated to select the claimed species of antibiotic and the claimed species of prostaglandin to obtain the claimed invention, as required in order to establish a *prima facie* case of obviousness (see M.P.E.P. §2144.08 (II)(A)(4)).

Neither Herschler nor Kelly discloses the vaginal administration of azithromycin. While the Examiner alleges that Kirschner discloses the vaginal administration of azithromycin, and combines it with Herschler and Kelly, which are alleged to teach the vaginal administration of prostaglandin, Applicants respectfully disagree one of ordinary skill in the art would find it obvious that the synergistic effect produced by the administration of both azithromycin and misoprostol, would have been obvious to one of ordinary skill in the art. Any such effect would have not been reasonably predictable firstly on the basis that the effect of a combination of azithromycin with a prostaglandin both administered vaginally had never been done before and secondly on the basis that the prior art teaches so many possible combinations of ingredients to be administered vaginally, that limiting the invention to the vaginal administration of azithromycin and misoprostol would not have been considered by any person of ordinary skill in art. As previously noted in prior responses, Kirschner refers to a long list of many therapeutically active drugs for administration such as antifungal agents, antiviral agents, spermicides, surface active drugs, androgenic substances, for use with a wide selection of delivery systems such as dispersions, solids, suspensions, ointments, pastes, powders, foams, creams, jellies, sprays, gels, tablets, sponges and patches. Reference to azithromycin in Kirschner is limited to a passing mention in a long list of many other antibacterial agents as part of a larger list of many therapeutically active drugs. Moreover, there is no mention of prostaglandin or misoprostol. Similarly, misoprostol is only listed as one of several examples of a prostaglandin in Kelly. There are so many possible combinations of ingredients that could have been administered based upon a combination of Kirschner and either Herschler or

Kelly, that one of skill in the could not have reasonably predicted the result uncovered by the Applicant.

Thus, considering the express teaching of the references, one of ordinary skill in the art would not have been able to combine the references to provide for the administration of azithromycin vaginally with mistoprostol in order to treat various pelvic infections. There is simply no teaching or suggestion of that in any of the references and/or in any combination of the references, that azithromycin and misoprostol can be administered vaginally. Even if the Examiner takes the position that Kirschner et al. provides for the vaginal administration of azithromycin, it does not provide for the vaginal administration of BOTH azithromycin and misoprostol. Simply asserting that it would have been obvious to do so can only be done in hindsight and would not be viewed by one of skill in the art as “predictable” prior to Applicant’s invention.

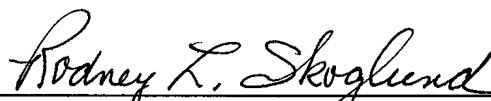
It has been found in the present invention that co-administration of an antibiotic, namely azithromycin, and a prostaglandin, namely misoprostol, or administration of misoprostol followed by azithromycin, is advantageous because of a synergistic effect between the antibiotic and prostaglandin as disclosed in the application. In this way, the collagenolytic properties of misoprostol helps to break apart collagen in the tissue at the site of administration and allows for easier absorption of the azithromycin into the target tissue. Thus, the treatment of pelvic tissue infection is improved. Nowhere is this affect shown in any of the prior art and, given the area of infection and the ingredients employed, it would not have been predictable. Furthermore, the Examiner has made no express findings of fact that would have lead to his contention that the combination of the prior art supports a *prima facie* case of obviousness. See M.P.E.P. §2144.08 (II)(A)(4)(f).

Finally, Applicant notes that new claims 56 and 57 have been added to include a range of amounts of azithromycin and misoprostol used in the invention. Support for these amendments can be found at page 6, lines 1-5.

In light of the foregoing, reconsideration of all pending claims 40-57 is respectfully requested, and a Notice of Allowance of those claims is earnestly solicited. Should the Examiner wish to discuss any of the foregoing in greater detail, the undersigned attorney would welcome a telephone call.

In the event that a fee required for the filing of this document is missing or insufficient, the undersigned attorney hereby authorizes the Commissioner to charge payment of any fees associated with this communication or to credit any overpayment to Deposit Account No. **18-0987**.

Respectfully submitted,


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Attorney Docket No. BBD.P.22

March 24, 2010